Applicant: Suk Cho et al. Attorney's Docket No.: 09143-017001

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REMARKS

Claims 1-30 and 32-34 were pending. In the Office Action dated February 3, 2003, the Examiner maintained the rejection of record of claims 1-30 and 32-34 under 35 U.S.C. § 103(a) over Perkes (WO 99/07400, hereinafter "Perkes") and/or Gaynor *et al.* (U.S. Pat. No. 5,904,924, hereinafter "Gaynor"). Applicants filed a Notice of Appeal (with requisite fee and extension of time fee and petition) on July 3, 2003, thereby extending the period for reply to September 3, 2003. In this Submission filed concurrently with their Request for Continued Examination under 37 C.F.R. § 1.114, Applicants have cancelled claim 32 without prejudice to further prosecution and amended claim 33. Accordingly, claims 1-30 and 32-34 are pending. Applicants ask that the claims be reconsidered and allowed in view of the amendments and the following remarks.

Rejections under 35 U.S.C. § 103(a)

In the office action dated February 3, 2003, the Examiner maintained the rejection of claims 1-30 and 32-34 under 35 U.S.C. § 103(a) over Perkes and/or Gaynor, stating in particular that "applicant has not provided comparisons related to the results obtained by using that particularly claimed variety of grape seed [Muscat] extract. . . . It is suggested that applicant demonstrate, via a side-by-side comparison, the results obtained when using the grape seed extract of the cited reference and those results obtained by utilizing the claimed Muscat grape seed extract."

Applicants respectfully disagree. Proper analysis under § 103 requires consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition, and (2) whether the prior art would also have revealed that in so making, those of ordinary skill would have had a reasonable expectation of success. In re Vaeck, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). Claims 1-24 are directed to a dietary supplement comprising a grape skin extract and a Muscat variety grape seed extract. The Perkes reference discloses three formulations containing grape skin extracts and

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grape seed extracts. The Perkes reference, however, does not teach or suggest any composition containing a grape skin extract in combination with a <u>Muscat</u> variety grape seed extract, as present claims 1-24 require. At no point does the Perkes reference suggest the combination of a grape skin extract and a Muscat variety grape seed extract. In fact, the Perkes reference never mentions combining a Muscat variety grape seed extract with a grape skin extract to form the presently claimed composition. Thus, the cited reference fails to suggest that a person having ordinary skill in the art should make the presently claimed invention.

As additional evidence of nonobviousness, Applicants note that compositions containing a grape skin extract in combination with a Muscat grape seed extract exhibit surprisingly high reductions in platelet aggregation activity. For example, the Perkes reference teaches achieving reductions in platelet aggregation activity of $40\% \pm 9\%$ and $42\% \pm 10\%$. See Perkes reference at pages 24 and 27. Applicants' specification, on the other hand, teaches a reduction in platelet aggregation activity of 60% with a composition having a grape skin extract in combination with a Muscat grape seed extract. See Specification at pages 18-19. As explained in the attached Declaration signed by Lynn Perkes, listed as an inventor on the present application and as an Inventor/Applicant on the Perkes reference, the difference between the $40\% \pm 9\%$ and $42\% \pm 10\%$ reductions reported in the Perkes reference and the 60% reductions reported in the present application is substantial and unexpected. Thus, contrary to the Examiner's position, the present claims are not obvious.

In light of the above, Applicants respectfully request the withdrawal of the rejections of claims 1-24 and 33-34 under 35 U.S.C. § 103(a).

The Examiner also maintained his rejection of claims 25-30 and 33-34 under 35 U.S.C. § 103(a) as being unpatentable over Gaynor *et al.* (U.S. Patent No. 5,904,924). Specifically, the Examiner stated that Gaynor discloses a nutritional powder having a grape skin extract and a grape seed extract at a ratio of 7.5 to 1, and that a ratio of 7.5 to 1 is within the same range as a ratio of 5 to 1 "such that the ratios practically overlap." The Examiner noted that Applicants

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could rebut a *prima facie* case of obviousness based on overlapping ranges by showing the criticality of the claimed ranges.

Applicants respectfully disagree. Claims 25-30 and 33-34 recite a dietary supplement containing a grape skin extract and a grape seed extract where the ratio of grape skin extract to grape seed extract is between 3 to 1 and 5 to 1. The only composition disclosed in the Gaynor *et al.* reference is a 969 gram mixture containing 300 mg of grape skin extract and 40 mg of grape seed extract, representing a 7.5 to 1 ratio of grape skin extract to grape seed extract, which the Examiner has acknowledged is not disclosed in the Gaynor *et al.* reference. The Gaynor *et al.* reference fails to teach or suggest any other ratio of grape skin extract to grape seed extract, or that a person having ordinary skill in the art should modify the amounts of grape skin extract and grape seed extract to obtain a supplement as presently claimed. Moreover, and importantly, a ratio of 7.5 to 1 is 50% larger than a ratio of 5 to 1. Contrary to the Examiner's assertion, when two numbers differ by 50%, they do not "practically overlap." Accordingly, the Examiner has not demonstrated a *prima facie* case of obviousness based on "overlapping ranges" under 35 U.S.C. 103(a).

In light of the above, claims 25-30 and 33-34 are not obvious under 35 U.S.C. § 103(a) and Applicants respectfully request the withdrawal of the rejections.

Finally, with respect to the rejection under 35 U.S.C. § 103(a) of claims 32 and 33, directed to dietary supplements containing a grape skin extract and a grape seed extract containing recited amounts of particular flavanols, Applicants have herein cancelled claim 32 without prejudice to further prosecution and have amended claim 33 appropriately, thereby rendering the rejection moot.

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CONCLUSION

Given all of the above, Applicants respectfully assert that the pending claims are in condition for allowance, which action is requested. The Examiner is invited to telephone the under-signed attorney if such would expedite prosecution.

Enclosed is a \$750.00 check for the Request for Continued Examination. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: 9/3/03

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